

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Patent Application of

**THOMPSON**

Appln. No. 09/287,354

Group Art Unit: 1653

Filing Date: April 7, 1999

Examiner: K. Carlson

FOR: HUMAN HAIRLESS GENE AND PROTEIN

**DECLARATION OF CATHERINE C. THOMPSON**

I, Catherine C. Thompson, of 503 Wingate Road, Baltimore, Maryland 21210, declare the following:

1. I earned a Ph.D. degree in 1989 from the University of California, San Diego.
2. I hold the position of Assistant Professor in the Department of Neuroscience at the Johns Hopkins University School of Medicine and the Kennedy Krieger Institute.
3. I believe I am the original, first, and sole inventor of the subject matter which is claimed in this patent application.
4. I have reviewed and understand the contents of this patent application.
5. I have read the Office Action mailed September 20, 2000.
6. On information and belief, I understand that the Examiner rejected claims 1-4, 6-7 and 9 because she alleges that Ahmad et al. (Science, 279:720-724, 1998) is prior art to my invention of the claimed subject matter. The Ahmad et al. reference does not anticipate claims 1-4, 6-7 and 9 because it has a publication date of January 30, 1998 and I had isolated a cDNA construct for the human Hairless gene (i.e., a polynucleotide) and determined the nucleotide sequence of its insert before January 30, 1998.

7. As evidence that I determined the nucleotide sequence of a cDNA construct for the human Hairless gene before the publication date of the Ahmad et al. reference, a computer printout has been attached that shows a FASTA comparison between the nucleotide sequence determined for the human Hairless cDNA insert (i.e., Hhr.Seq) and nucleotide sequences of the GenEMBL database. To preserve confidentiality, the date on the computer printout has been blacked out but it is a date before January 30, 1998.

8. The best score for the FASTA comparison was obtained with the nucleotide sequence of the mouse hairless gene. On pages 3-9 of the attachment, the human sequence is shown above and the mouse sequence is shown below.

9. The amino acid sequence of the human Hairless protein was determined by "translating" codons of the open reading frame of the nucleotide sequence of the human Hairless gene.

10. Thus, the Ahmad et al. reference is not prior art and does not anticipate claims 1-4, 6-7 and 9 because it was published after my invention of the claimed subject matter.

11. On information and belief, I understand that the Examiner rejected claims 1-9 because she alleges that Thompson (J Neurosci, 16:7832-7840, 1996) discloses the claimed subject matter. The Thompson (1996) reference does not anticipate claims 1-9 because it does not put the public in possession of the claimed subject matter.

12. The statement quoted by the Examiner in the Thompson (1996) reference on page 7839 supports the fact that I had determined the amino acid sequence of the human Hairless protein before January 30, 1998.

13. But the Thompson (1996) reference does not put the public in possession of the claimed invention because neither the cDNA construct (i.e., a polynucleotide) nor the

nucleotide sequence of its insert was disclosed. Without such a disclosure, the public could not practice the claimed invention.

14. Thus, the Thompson (1996) reference does not anticipate claims 1-9 because it does not put the public in possession of the claimed invention.

15. On information and belief, I understand that the Examiner rejected claims 1-9 because she alleges that the invention has been abandoned.

16. I deny that I abandoned the claimed invention. My 1996 and 1997 publications show that I did not abandon the invention.

17. When the Journal of Neuroscience article was written, I had isolated a cDNA construct for the human Hairless gene and determined the nucleotide sequence of its insert. But the cDNA construct did not contain a full-length insert and I did not know whether the partial sequence I had isolated would encode a functional protein.

18. On information and belief, I understood that to be granted a U.S. patent on my invention I would be required to show a "practical utility" (e.g., a function or activity of the human Hairless gene or protein) for the invention. From the predicted primary amino acid sequence, it was impossible to predict with reasonable certainty the biochemical function of the Hairless protein based on homology to known proteins and/or known functional motifs. Thus, determining the function of the Hairless protein was an ongoing research project in my laboratory. The mouse hairless gene's proposed function was related solely to the phenotype of a homozygous mutant *hr/hr* mouse, and a human mutation was not known at the time I made the invention.

19. My article in the Proceedings of the National Academy of Sciences shows that I was successful in determining a function of the Hairless protein. Chimeric or fusion proteins with a partial-length sequence from the Hairless protein exhibited transcriptional activity.

20. On the basis of my discovery that a partial-length sequence of the Hairless protein exhibited transcriptional activity (Thompson, Proc Natl Acad Sci USA, 94:8527-8532, 1997), a practical utility could be disclosed for my invention (e.g., the nucleotide and amino acid sequences of the human Hairless gene and protein, respectively).

21. Thus, the invention was not abandoned because I did not believe possession of the human Hairless sequences alone was sufficient to apply for a U.S. patent. Instead, on information and belief, my discovery that the full-length Hairless nucleotide sequence was not needed to produce a functional Hairless protein (i.e., having transcriptional activity) showed that my invention had a practical utility.

22. The undersigned declares that all statements made herein of my personal knowledge are true and that all statements made on information and belief are believed true; and further that these statements were made with the knowledge that any willful false statements are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that willful false statements may jeopardize the validity of this patent application or any patent issuing thereon.

Date: March 20, 2001

  
Catherine C. Thompson